

CLAIMS

We claim:

1. A freeze-dried preparation comprising methylcobalamin or a pharmacologically acceptable salt thereof and an excipient,

5 wherein at least one or more species of the excipient is in an amorphous state.

2. The freeze-dried preparation according to Claim 1, wherein the methylcobalamin or the pharmacologically acceptable salt thereof is also in an
10 amorphous state.

3. The freeze-dried preparation according to Claim 1 or 2, wherein the excipient which is in the amorphous state comprises a sugar.

15 4. The freeze-dried preparation according to any one of Claims 1 through 3, wherein the excipient further comprises a sugar alcohol.

5. The freeze-dried preparation according to any one of Claims 1 through 4, further comprising a pH adjuster.

20 6. The freeze-dried preparation according to any one of Claims 1 through 5, further comprising an anti-oxidant.

7. The freeze-dried preparation according to any one of Claims 1
25 through 4, wherein when the excipient comprises the sugar and the sugar alcohol,

the excipient in the amorphous state is contained in an amount of at least 20% by weight, based on the total weight of the sugar and the sugar alcohol.

8. A freeze-dried preparation comprising methylcobalamin or a
5 pharmacologically acceptable salt thereof and an excipient, the freeze-dried preparation obtained by a production process which comprises the steps of:
(a) dissolving the methylcobalamin or the pharmacologically acceptable salt thereof and the excipient in a solvent; and
(b) freeze-drying the solution so as to produce an amorphous state of at
10 least one or more species of the excipient.

9. The freeze-dried preparation according to Claim 8, wherein the freeze-drying in the step (b) is accomplished so as to further produce an amorphous state of the methylcobalamin or the pharmacologically acceptable salt thereof.

15 10. The freeze-dried preparation according to Claim 8 or 9, wherein the pre-freezing in the step (b) is performed at a temperature at which the excipient does not crystallize, or below the temperature.

20 11. The freeze-dried preparation according to any one of Claims 8 through 10, wherein the excipient which is in the amorphous state comprises a sugar.

12. The freeze-dried preparation according to any one of Claims 8
25 through 11, wherein the excipient further comprises a sugar alcohol.

13. The freeze-dried preparation according to any one of Claims 8 through 12, wherein a pH adjuster is also dissolved in the step (a).

14. The freeze-dried preparation according to any one of Claims 8 through 13, wherein an anti-oxidant is also dissolved in the step (a).

15. The freeze-dried preparation according to any one of Claims 8 through 12, wherein when the excipient comprises the sugar and the sugar alcohol, the excipient in the amorphous state is contained in an amount of at least 20% by weight, based on the total weight of the sugar and the sugar alcohol.

16. A process for producing a freeze-dried preparation comprising methylcobalamin which comprises the steps of:

(1) dissolving the methylcobalamin or a pharmacologically acceptable salt thereof and an excipient in a solvent; and

(2) freeze-drying the solution so as to produce an amorphous state of at least one or more species of the excipient.

17. The process according to Claim 16, wherein the freeze drying in the step (2) is performed so as to further produce an amorphous state of the methylcobalamin or the pharmacologically acceptable salt thereof.

18. The process according to Claim 16 or 17, wherein the pre-freezing in the step (2) is performed at a temperature at which the excipient does not crystallize, or below the temperature.

19. The process according to any one of Claims 16 through 18, wherein the excipient in the amorphous state comprises a sugar.

20. The process according to any one of Claims 16 through 19, wherein
5 the excipient further comprises a sugar alcohol.

21. The process according to any one of Claims 16 through 20, wherein the freeze-dried preparation further comprises a pH adjuster.

10 22. The process according to any one of Claims 16 through 21, wherein the freeze-dried preparation further comprises an anti-oxidant.

23. The process according to any one of Claims 16 through 22, wherein when the excipient comprises the sugar and the sugar alcohol, the excipient in the
15 amorphous state is contained in an amount of at least 20% by weight, based on the total weight of the sugar and the sugar alcohol.